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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/798,623

03/10/2004

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EXAMINER

HORNBERGER, JENNIFER LEA

ART UNIT

PAPER NUMBER

3734

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/798,623	Applicant(s) WULFMAN ET AL.	
	Examiner JENNIFER L. HORNBERGER	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/02/2005, 12/18/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Priority***

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 09/826,487, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The parent application fails to provide support for "pressure at the liner distal terminal end at least substantially equals the pressure of the lumen at the intersect area." Accordingly, claims 6-9 and 13 are not entitled benefit of the prior-filed application.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-5, 10, 12, and 15-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Keith et al. (US 5,938,670).

Regarding claim 1, Keith et al. disclose an assembly for creating a liquid seal in a medial device, the assembly comprising: a liner (79) wrapped around a rotatable torque tube (42) to form a flood space there within; the liner extending longitudinally along at least a portion of the torque tube, and a sealing member with an infusion port (126) for infusing a sufficient amount of liquid in the flood space to create a seal around the torque tube.

Regarding claim 2, Keith et al. disclose the flood space includes a clearance area between the liner and the torque tube.

Regarding claim 3, Keith et al. disclose the torque tube is a coiled drive shaft and the flood space includes gaps between the coils (Fig. 3,4).

Regarding claim 4, Keith et al. disclose the torque tube (42) includes a lumen (43) for a guidewire (45) and the flood space includes the lumen.

Regarding claim 5, Keith et al. disclose a suction port (76) for aspirating fluid from a lumen (80) (col. 10, ln. 46-53) and wherein the liner separates a lower pressure in the flood space from adjacent higher pressure outside or proximal to the flood space (col. 11, ln. 65-67).

Regarding claim 10, Keith et al. disclose the sealing member further comprises an overflow port (sealing bearing 56) for exit of excess liquid and wherein the torque tube extends through the overflow port.

Regarding claim 12, Keith et al. disclose an assembly for creating a liquid seal in a medial device, the assembly comprising: a liner (79) wrapped around a rotatable torque tube (42) to form a flood space there within; the liner extending longitudinally along at least a portion of the torque tube, and a sealing member

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with an infusion port (126) for infusing a sufficient amount of liquid in the flood space to create a seal around the torque tube, and a suction port (76) for aspirating fluid from a lumen (80) extending within a catheter enclosing the liner; wherein the liner separates adjacent pressure outside or proximal to the flood space from the pressure in the flood space (col. 11, ln. 65-67).

Regarding claim 15, Keith et al. disclose a medical device comprising: a rotatable torque tube (42); a catheter (70) enclosing at least a portion of the torque tube; and a sealing assembly comprising: a liner (79) wrapped around a rotatable torque tube to form a flood space there within, the liner extending longitudinally along at least a portion of the torque tube and a sealing member with an infusion port (126) for infusing a sufficient amount of liquid in the flood space to create a seal around the torque tube.

Regarding claim 16, Keith et al. disclose a drive system (10) coupled to the torque tube to rotate the torque tube.

Regarding claim 17, Keith et al. disclose a hand held unit and the sealing assembly housed within the hand held unit.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 6-9 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith et al. in view of Shadduck (US 2002/0095147).

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Regarding claim 6, Keith et al. disclose the liner a distal terminal end at an intersect area within the catheter (col. 13, ln. 20-22) but fails to disclose the pressure at the liner distal terminal end at least substantially equals the pressure of the lumen in the intersect area. However, Shadduck discloses it is well known in the art to balance the aspiration and irrigation pressures to allow the fluid to circulate through the system and to prevent overpressures in the working space. Therefore, it would have been obvious to one of ordinary skill to have made the pressure at the distal end of the liner the same as the lumen at the intersect area. Regarding claim 7, it directly follows that the liquid traveling in the flood space would be forced by the irrigation pressure to exit the flood space and forced by the aspiration pressure into the lumen.

Regarding claim 8, Keith et al. disclose the liner has a length that reduces fluid flow rate and restricts the amount of liquid exiting the flood space (col. 12, ln. 3-34).

Regarding claim 9, Keith et al. disclose the claimed invention except for the liner length being between 6 and 30 inches. It would have been obvious to one having ordinary skill in the art at the time the invention was made to optimize the length of the liner, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claim 13, Keith et al. disclose the liner a distal terminal end at an intersect area within the catheter (col. 13, ln. 20-22) but fails to disclose the pressure at the liner distal terminal end at least substantially equals the pressure of the lumen in the intersect area. However, Shadduck discloses it is well known in the art to balance the aspiration and irrigation pressures to allow the fluid to

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circulate through the system and to prevent overpressures in the working space.

Therefore, it would have been obvious to one of ordinary skill to have made the pressure at the distal end of the liner the same as the lumen at the intersect area.

Regarding claim 14, it directly follows that the liquid traveling in the flood space would be forced by the irrigation pressure to exit the flood space and forced by the aspiration pressure into the lumen.

5. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keith et al. in view of Masch (US 4,728,319) and Shturman (US 5,295,958).

Regarding claim 11, Keith et al. fail to disclose the liquid is blood that has been extracted from the patient during use of the medical device on the patient. Masch discloses an intravascular catheter for cutting blood vessel blockages. Masch discloses communicating an oxygen-rich fluid such as blood through a rotating cutter to flush out fragments of the blockage and to provide the vessel with sufficient oxygen so that it remains in healthy condition (col. 7, ln 1-4 and col 7, ln. 65 - col. 8, ln -7). Shturman discloses blood and calcification deposits aspirated into a catheter and the blood filtered to remove debris and then returned to the blood vessel (col. 9, ln. 23-36). It would have been obvious to one of ordinary skill to have used oxygen rich blood as taught by Masch because it would help to maintain the vessel and to have used blood extracted from the patient as taught by Shturman because it would prevent potentially adverse reactions to donor blood.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number

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is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/
Primary Examiner, Art Unit 3734

jlh
3/13/08